

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

Awapatent AB  
Box 11394  
404 28 Göteborg  
Sverige

**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 19 MAY 2005

PCT

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

12-05-2005

Applicant's or agent's file reference  
21017477

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.  
PCT/SE 2004/001883

International filing date (day/month/year)  
16.12.2004

Priority date (day/month/year)  
30.01.2004

International Patent Classification (IPC) or both national classification and IPC  
G01N 33/53, G01N 33/573, G01N 33/569

Applicant

Tendera AB et al

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/SE  
Patent- och registreringsverket  
Box 5055  
S-102 42 STOCKHOLM  
Facsimile No. +46 8 667 72 88

Authorized officer

Terese Persson/EÖ

Telephone No. +46 8 782 25 00

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2004/001883

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/SE 2004/001883

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement		
Novelty (N)	Claims	1-41 YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims	1-41 NO
Industrial applicability (IA)	Claims	1-41 YES
	Claims	NO
2. Citations and explanations:		
Documents cited in the International Search Report:		
D1: Chapple I.L.C., "Periodontal disease diagnosis: current status and future developments", Journal of Dentistry, 1997, Vol. 25, No. 1, pages 3-15		
D2: Cox SW. et al., "A simple, combined fluorogenic and chromogenic method for the assay of proteases in gingival cervical fluid", Journal of Periodontal Research, 1990, Vol. 25, pages 164-171		
D3: US 5328829 A		
D4: Tan KS. et al., "Bacteroides forsythus prtH genotype in periodontitis patients: occurrence and association with periodontal diseases", Journal of Periodontal Research, 2001, Vol. 36, pages 398-403		
D5: US 6280687 B1		
D6: Eley B.M. et al., "Correlation Between Gingivain/Gingipain and Bacterial Dipeptidyl Peptidase Activity in Gingival Cervicular Fluid and Periodontal Attachment Loss in Chronic Periodontitis Patients. A 2-Year Longitudinal Study", Journal Periodontol, 1996, Vol. 67, pages 703-716		
D7: Armitage Gary C. et al., "Longitudinal Evaluation of Elastase as a Marker for the Progression of Periodontitis", Journal Periodontol, 1994, Vol. 65, pages 120-128		
<p>The present application relates to diagnosis of periodontal disease by combining detection of a substance originating from bacteria and a substance originating from the immune or inflammatory system of the patient. By combining both types of substances, a statistically more significant test is obtained (experimental support for the combination of elastase from human neutrophils and arg-gingipain from <i>P. gingivalis</i> is given).</p>		

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2004/001883

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D1 discloses a number of sources of potential markers for periodontal disease. Mentioned are e.g. markers indicating the presence of putative periodontal pathogens and markers of the host's immune response to certain pathogenic species. Specifically mentioned are e.g. bacterial products such as trypsin-like enzymes and host markers such as elastase and TNF-alpha. D1 also suggests that by combining two or three markers in a single test, one may provide a more accurate mean of diagnosis of periodontal disease. (Page 7, column 2, paragraph 3-page 8, column 2, paragraph 1; table 1.)

Thus, the subject matter claimed in claims 1 and 23-24 differs from D1 since no method/kit is actually provided, it is only suggested. Even though no specific examples of combination is given in D1, it is considered to lie close to hand for a person skilled in the art to select and test suitable combinations for obtaining a more accurate test, as suggested in the document. Therefore, combining the type of substances claimed in claims 1 and 23-24 is not considered to involve an inventive step.

Additional makers as claimed in claims 3-16 and 25-38 are all known to be markers for periodontal disease. Therefore, the subject matter claimed in claims 3-16 and 25-38 is considered to be merely representing straightforward possibilities which the skilled person would select from several possibilities, in accordance with circumstances, without the exercise of inventive skill. The subject matter of said depending claims is therefore considered to be obvious to the skilled person in the absence of any demonstrated unexpected or special results.

Additional features as claimed in claims 2, 17-22 and 39-41 are considered to be detailed executions obvious for a person skilled in the art. Therefore, the subject matter claimed in claims 2, 17-22 and 39-41 are considered to lack an inventive step.

D2-D7 are considered to disclose the general state of the art.

To summarise, the subject matter claimed in claims 1-41 is novel but is considered to lack an inventive step. The subject matter claimed in claims 1-41 is considered to be industrially applicable.

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

Awapatent AB  
Box 11394  
404 28 Göteborg  
Sverige

**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 19 MAY 2005

PCT

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

12-05-2005

Applicant's or agent's file reference  
21017477

## FOR FURTHER ACTION

See paragraph 2 below

International application No.  
PCT/SE 2004/001883

International filing date (day/month/year)  
16.12.2004

Priority date (day/month/year)  
30.01.2004

International Patent Classification (IPC) or both national classification and IPC  
G01N 33/53, G01N 33/573, G01N 33/569

Applicant

Tendera AB et al

### 1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/SE  
Patent- och registreringsverket  
Box 5055  
S-102 42 STOCKHOLM  
Facsimile No. +46 8 667 72 88

Authorized officer

Terese Persson/EÖ

Telephone No. +46 8 782 25 00

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2004/001883

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/SE 2004/001883

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement	
Novelty (N)	Claims <u>1-41</u> YES Claims _____ NO
Inventive step (IS)	Claims _____ YES Claims <u>1-41</u> NO
Industrial applicability (IA)	Claims <u>1-41</u> YES Claims _____ NO
2. Citations and explanations:	
<p>Documents cited in the International Search Report:</p> <p>D1: Chapple I.L.C., "Periodontal disease diagnosis: current status and future developments", Journal of Dentistry, 1997, Vol. 25, No. 1, pages 3-15</p> <p>D2: Cox SW. et al., "A simple, combined fluorogenic and chromogenic method for the assay of proteases in gingival cervical fluid", Journal of Periodontal Research, 1990, Vol. 25, pages 164-171</p> <p>D3: US 5328829 A</p> <p>D4: Tan KS. et al., "Bacteroides forsythus prtH genotype in periodontitis patients: occurrence and association with periodontal diseases", Journal of Periodontal Research, 2001, Vol. 36, pages 398-403</p> <p>D5: US 6280687 B1</p> <p>D6: Eley B.M. et al., "Correlation Between Gingivain/Gingipain and Bacterial Dipeptidyl Peptidase Activity in Gingival Cervicular Fluid and Periodontal Attachment Loss in Chronic Periodontitis Patients. A 2-Year Longitudinal Study", Journal Periodontol, 1996, Vol. 67, pages 703-716</p> <p>D7: Armitage Gary C. et al., "Longitudinal Evaluation of Elastase as a Marker for the Progression of Periodontitis", Journal Periodontol, 1994, Vol. 65, pages 120-128</p> <p>The present application relates to diagnosis of periodontal disease by combining detection of a substance originating from bacteria and a substance originating from the immune or inflammatory system of the patient. By combining both types of substances, a statistically more significant test is obtained (experimental support for the combination of elastase from human neutrophils and arg-gingipain from <i>P. gingivalis</i> is given).</p>	

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2004/001883

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.  
Continuation of: BOX V

D1 discloses a number of sources of potential markers for periodontal disease. Mentioned are e.g. markers indicating the presence of putative periodontal pathogens and markers of the host's immune response to certain pathogenic species. Specifically mentioned are e.g. bacterial products such as trypsin-like enzymes and host markers such as elastase and TNF-alpha. D1 also suggests that by combining two or three markers in a single test, one may provide a more accurate mean of diagnosis of periodontal disease. (Page 7, column 2, paragraph 3-page 8, column 2, paragraph 1; table 1.)

Thus, the subject matter claimed in claims 1 and 23-24 differs from D1 since no method/kit is actually provided, it is only suggested. Even though no specific examples of combination is given in D1, it is considered to lie close to hand for a person skilled in the art to select and test suitable combinations for obtaining a more accurate test, as suggested in the document. Therefore, combining the type of substances claimed in claims 1 and 23-24 is not considered to involve an inventive step.

Additional makers as claimed in claims 3-16 and 25-38 are all known to be markers for periodontal disease. Therefore, the subject matter claimed in claims 3-16 and 25-38 is considered to be merely representing straightforward possibilities which the skilled person would select from several possibilities, in accordance with circumstances, without the exercise of inventive skill. The subject matter of said depending claims is therefore considered to be obvious to the skilled person in the absence of any demonstrated unexpected or special results.

Additional features as claimed in claims 2, 17-22 and 39-41 are considered to be detailed executions obvious for a person skilled in the art. Therefore, the subject matter claimed in claims 2, 17-22 and 39-41 are considered to lack an inventive step.

D2-D7 are considered to disclose the general state of the art.

To summarise, the subject matter claimed in claims 1-41 is novel but is considered to lack an inventive step. The subject matter claimed in claims 1-41 is considered to be industrially applicable.